GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1377
ANSWERED ON:30.07.2003
SUB-STANDARD DRUGS
A. VENKATESH NAIK;ASHOK NAMDEORAO MOHOL;GADDE RAMAMOHAN;M.V.V.S MURTHI;PUSHPDAN SHAMBHUDAN GADHAVI;RAGHUNATH JHA;RAMJI MANJHI;RAMSHETH THAKUR;SRIPRAKASH JAISWAL;T. GOVINDAN

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government are aware of the fact that sub-standard drugs are being supplied by various suppliers;

(b) if so ,whether the Government propose to investigate the matter;

(c) if so, the details thereof and penal actions to be taken against the persons found responsible;

(d) if not, the reasons therefor;

(e) the number of cases of spurious drugs which came to the notice of the Government during the last three years; and

(f) the steps taken by the Government in each case ?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI. A. RAJA)

(a) to (d): Government of India is making every effort to ensure that drugs of standard quality are supplied under the various disease control programmes. In case any specific instance of sub-standard drug being supplied comes to notice, suitable remedial action is immediately taken to get the supplies replaced and to take action against the suppliers.

(e) & (f): As per the feedback available from the State Drug Control Administration, a statement indicating number of spurious medicines detected during the period 2000-01; 2001-02 and 2002-03 is at Annex. − I.

Under the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder, the responsibility for regulating manufacture and sale of drugs including monitoring their quality is vested with the State Governments. The State Governments are advised from time to time to gear up their enforcement machinery to detect and unearth spurious/fake drugs moving in the inter-state commerce as well as to provide and strengthen their regulatory infrastructure; to establish their own State level testing labs. to ensure speedy analysis of drug samples for which they are provided assistance to strengthen and augment their infrastructure facilities in their lab. The State Governments have also been advised to keep strict surveillance over the suspected dealers; collection of survey samples under National Survey Quality Evaluation of Drugs (NSQED) programme; constitution/reactivation of state drug advisory committees in which various trade and industry association as well as consumer associations can file representations; establishment of separate intelligence-cum-legal cell; to develop efficient communication facilities and recall procedures; engaging experienced counsel for fighting spurious drug cases etc.

Governemnt of India has taken the following initiatives to tackle the problem of spurious drugs:-

(i) Detailed guidelines in respect of strategies required to be adopted for efficient surveillance over the movement of spurious drugs were given to States on November 17, 1999 to ensure focused surveillance over manufacture and sale of spurious drugs.

(ii) Issues concerning alleged sale of spurious drugs was taken up by Union Health Minister with State Health Ministers in the 7th Conference of Central Council of Health (CCH) & FW held on 12 −13 July, 2001CCH resolved that in order to address issues relating to the increasing reports of spurious drugs/counterfeit drugs, special attention required to be given to monitor and unearth such illegal activities by constituting a separate intelligence-cum-legal cell in the respective drug control organization and in seeking cooperation of the pharma industry, trade as well as the police.

(iii) Department of Health constituted a broad based Committee under the Chairmanship of DGHS in July, 2001 to examine issues concerning the problem of spurious drugs. The observations and recommendations of this Committee have been circulated on September 16, 2002 to all State Drugs Controllers for their information and necessary action in the matter.

(iv) Union Minister of Health and Family Welfare had specifically written to all Chief Ministers on October 8, 2002 on the issue of spurious drugs, seeking their personal intervention to ensure that adequate measures are taken in each State to vigorously pursue the strategies needed to preclude any possibility of menace of spurious products so as to collectively ensure its total eradication.

(v) A meeting of Health Ministers and Senior Officials of 13 major States of the country was convened by Union Minister of Health and Family Welfare on 12.11.2002 to ensure concerted action to check any possible movement of spurious drugs in the country and to involve all stake holders to fight this menace. Suggestions/views which emerged out of discussion were forwarded on January 8, 2003 to all the State Governments for their information and necessary action. One of the recommendations which emerged as outcome of discussion, was enactment of "The Gujarat Prevention of Anti-social Activities Act, 1985" (PASA) by the State Governments for deterrent action against offenders.

(vi) In order to increase the number of drug samples tested in the country and to bring down the reporting time to less than a month as against 3 to 6 months presently being taken by many laboratories, a comprehensive plan has been undertaken by Central Government under a capacity building project to be implemented with World Bank assistance.

(vii) In order to ensure speedy information exchange and networking of all States and Central Drugs Control Offices and Laboratories, a computerization project has been undertaken by Central Government.

(viii) A specialized training programme for drugs control officers of all State Governments responsible for keeping surveillance over possible movement of spurious drugs has been formulated and was conducted from 25th June, 2003 by Central Governemnt in cooperation with FDA, Maharashtra at Mumbai.

(ix) Government of India have constituted a Committee of experts on January 27, 2003 under the Chairmanship of Dr. R.A. Mashelkar, Director General, Council for Scientific and Industrial Research (CSIR) to undertake a comprehensive review of the drugs regulatory system in the country including the problem of spurious and substandard drugs and recommend remedial measures to deal with this problem effectively. The Committee has held two meetings on 26.2.2003 and 17.7.2003 to undertake focused examination of two distinct areas of its terms of reference. Consultations with number of eminent persons and stakeholders has also been undertaken. One of the issues to be addressed by this committee is to introduce highly stringent and deterrent punishment for drug offenders.

STATEMENT SHOWING STATEWISE NUMBER OF SPURIOUS MEDICINES DETECTED BY STATE DRUGS LICE AUTHORITIES DURING THE PERIOD 2000-01, 2001-02 AND 2002-03

S. No.	STATES/UTs	2000-01	2001-02	2002-03
1.	ANDHRA PRADESH	27	4	6
2.	ARUNACHAL PRADESH	NIL	NIL	NIL
3.	ASSAM	NIL	1	NIL
4.	BIHAR	3	3	3
5.	GOA	NIL	NIL	NIL
6.	GUJARAT	2	2	5
7	HARYANA	15	42	13
8.	HIMACHAL PRADESH	NIL	NIL	1
9.	JAMMU AND KASHMIR	NIL	1	1
10.	KARNATAKA	NIL	4	1
11.	KERALA	NIL	NIL	NIL
12.	MADHYA PRADESH	1	2	NIL
13.	MAHARASHTRA	3	3	21
14.	MANIPUR	NIL	NIL	NIL
15.	MEGHALAYA	NIL	NIL	NIL
16.	MIZORAM	NIL	NIL	NIL
17.	NAGALAND	NIL	NIL	NIL
18.	ORISSA	NIL	NIL	1
19.	PUNJAB	17	4	16
20.	RAJASTHAN	13	20	7
21.	SIKKIM	NIL	NIL	NIL

22.	TAMILNADU	4	NIL	8
23.	TRIPURA	NIL	NIL	NIL
24.	UTTAR PRADESH	19	3	30
25.	WEST BENGAL	1	2	6
26.	PONDICHERRY	NIL	NIL	NIL
27.	A & NICOBAR ISLANDS	NIL	NIL	NIL
28.	CHANDIGARH	NIL	NIL	NIL
29.	DELHI	7	5	10
30.	DADRA & NAGAR HAVELI	NIL	NIL	NIL
31.	DAMAN & DIU	NIL	NIL	NIL
32.	LAKSHADWEEP	NIL	NIL	NIL
	TOTAL	112	96	129